

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK**

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**ONY, INC.,**

**Plaintiff,**

**- vs -**

**DECLARATION**

**Case No. 1:11-cv-01027-WMS**

**CORNERSTONE THERAPEUTICS, INC.,  
CHIESI FARMACEUTICI S.P.A.,  
NATURE AMERICA, INC.,  
d/b/a Nature Publishing Group,  
EDWARD E. LAWSON, M.D.,  
AMERICAN ACADEMY OF PEDIATRICS,  
PREMIER, INC., d/b/a Premier Research Services,  
RANGASAMY RAMANATHAN, M.D.,  
JATINDER J. BHATIA, M.D.,  
FRANK R. ERNST, PHARM.D. and  
KRISHNAMURTHY C. SEKAR, M.D.,**

**Defendants.**

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STATE OF NEW YORK                    )  
                                                  ) SS.:  
COUNTY OF ERIE                    )

EDMUND A. EGAN, M.D. declares the following to be true under penalty of perjury pursuant to 28 U.S.C. § 1746:

1. I am a licensed physician practicing the specialty of neonatology/perinatology and am President of the plaintiff ONY, Inc. ("ONY"). As such, I am fully familiar with the facts set forth in this declaration and make this declaration on my own knowledge in reply on ONY's pending motion for expedited discovery. In particular, I make this declaration to show why ONY did not "delay" or "wait" in either bringing this action or in seeking expedited discovery herein.

2. I first learned of the article which is the subject of this action (the "Article"), as e-published by the Journal of Perinatology (the "Journal") in September 2011, when a professional colleague brought it to my attention in mid-September. I immediately recognized the Article's assertion that ONY's surfactant Infasurf® had a higher mortality rate than the competing product Curosurf® (as manufactured by defendants Chiesi Farmaceutici S.P.A. ("Chiesi") and distributed in the United States by defendant Cornerstone Therapeutics, Inc. ("Cornerstone")) was false and misleading because it omitted Length of Stay ("LOS") data. Simply put, a newborn who dies early has a shorter LOS than a newborn who survives birth complications (such as Respiratory Distress Syndrome, or "RDS," which surfactants are used to treat) and therefore requires further treatment (and a longer hospital stay). By omitting the LOS data, the Article falsely asserted that the difference in mortality was attributable to the efficacy of the surfactant administered, when the LOS data would have made clear that the difference was instead a function of differences in the relative health of the two different patient universes.

3. It was also readily apparent to me that the Article was in essence an "infomercial" paid for by Cornerstone and Chiesi. Indeed, even according to the Article itself, it was "sponsored" by Chiesi and three of its four "authors" were "consultants" to Chiesi.

4. On or about September 20, 2011, I began hearing anecdotal information that Cornerstone was distributing the Article to health professionals at national meetings as a promotional piece touting the superior mortality of Curosurf®. Such sales pitches are typically made to busy clinicians unskilled in detecting data manipulation and unaware of any omitted data and its significance, and are thus fertile ground for the seeds of deception. Indeed, that is precisely why the FDA so stringently regulates advertising by pharmaceutical companies (which Cornerstone and Chiesi were evidently doing an end run around).

5. Complicating things is the fact that hospitals typically make an institutional decision on which surfactant(s) to include on their formulary. Changing from one product to another requires a change in policy that takes several months to execute. As a result, ONY would not necessarily immediately learn if and when a particular hospital or other customer made a decision to use Curosurf® over Infasurf® on a going forward basis because of a misleading spiel premised on the Article; indeed, the harm to ONY may not materialize for months or even longer.

6. Because these 2011 circumstances were so much different than those presented by certain earlier 2007 presentations (as discussed below), I immediately (on September 22, 2011) sent the letter included within **Exhibit A** hereto to the executive director of the defendant Academy of Pediatrics ("AAP," the sponsor of the Journal of Perinatology) and defendant Dr. Edward E. Lawson (the editor of the Journal of Perinatology, which is owned and published by defendant Nature America, Inc. ("Nature")). In that letter, I explained why the Journal should retract the false and misleading Article – the swiftest, surest way to prevent the competitive and public harm occasioned by Chiesi and Cornerstone's initial publication and subsequent dissemination of the deceptive piece.

7. In response, the AAP simply disavowed the Article. For its part, on October 12, 2011, the defendant Nature declined to retract the Article. Two days later, on October 14, 2011, I requested further reconsideration based on a concern my previous communication had been misunderstood. *See Exhibit A*. When no reply to the request for reconsideration was timely received, ONY directed its lawyers to send the October 31, 2011 more formal demand for retraction annexed hereto as **Exhibit B**, asking for a response within one week.

8. When that response did not materialize by mid-November (other than by the AAP again deferring to Nature), I instructed ONY's lawyers to file suit. Within two weeks, they did so – a not unreasonable period of time given the number of evidently complicit parties, the available claims against them, and the rather nuanced nature of some of those claims.

9. Even at that, however, ONY still found itself without the hard evidence it would need to satisfy its burden on a preliminary injunction motion seeking to enjoin further commercial dissemination of the Article by Cornerstone and/or Chiesi. As noted above, the evidence that ONY had of Chiesi and Cornerstone's post-publication use of the Article for competitive purposes was, at best, second hand. Also, while Chiesi's "fingerprints" were all over the Article, that evidence was circumstantial/inferential rather than direct. Accordingly, ONY also directed its attorneys to seek discovery on those issues in aid of a preliminary injunction motion as expeditiously as they could (which they did by their filing of this motion on December 8, 2011).

10. Accordingly, ONY has at all times acted with all available dispatch. Certainly, it should not be "penalized" – as the defendants seek to do – for having resorted to the Court as a last, rather than first, resort.

11. The other "delay" invoked by defendants is their own four-year delay in actually having their 2007 presentations published. Nothing about those 2007 presentations, however, suggested that ONY need do anything about them at that time (or since).

12. First, those 2007 presentations were what are known as "abstracts," which by their very nature are preliminary and tentative; they are merely presented to a small group of physicians in attendance at a meeting or conference, and are not widely published. For that

reason, such "abstracts" rarely have any impact on the scientific or medical community unless they are followed up by a published, peer-reviewed paper or article.

13. Indeed, such limited utility of research presented only in "abstract" form is recognized by the Journal itself, which has adopted the Uniform Requirements for Manuscript Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications, which state plainly: "Avoid using abstracts as references." See **Exhibit C** at p. 5.

14. It was against this backdrop that ONY learned of the 2007 presentations. The May 2007 presentation – which purported to present Curosurf®'s superior mortality – was the first to catch ONY's eye, since it was contrary to ONY's own data. When the October 2007 presentation – which reported based on the same data that infants treated with Curosurf® had a shorter LOS – the anomaly was explained: the Curosurf® babies were healthier to begin with.

15. That even the 2007 presenters – some of the authors here – considered their May 2007 mortality data defective was confirmed when they never submitted their findings for peer-reviewed publication as an article – until, that is, 2011, whereupon ONY immediately took the action outlined above.

16. Unlike mere abstracts (such as the 2007 presentations), published, peer-reviewed articles (especially those published in periodicals with the prestige and renown of the Journal) have considerable "precedential" value. For the reasons discussed above, abstracts presented at conferences have little "currency" post-presentation; they typically never again see the light of day, and have no lasting impact unless and until published in a peer-reviewed, respected journal. Once so published, however, especially in a journal as prestigious as the Journal, such papers assume an air of authority and respectability for years to come.

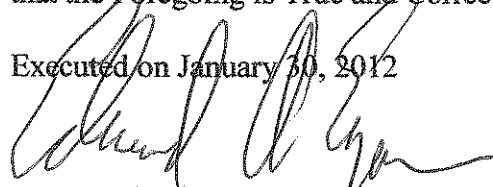
17. Of course, that authority and respectability is earned only if it is the result of the scientific method rather than commercial preordination and collusion. As the complaint herein alleges, the Article was the latter. The fact that ONY did not "jump the gun" in response to the scientifically and commercially meaningless 2007 presentations should no more count against it (as the defendants now urge) than its initial non-judicial efforts to avoid litigation by seeking the pre-suit retraction which would have rendered moot any need for judicial intervention.

18. Of course, the delay in reckoning advocated by the defendants serves their interests by allowing them to continue their deceit unfettered — especially if ONY is unable to discover who exactly it is they are deceiving and exactly how they are doing so in order to support a preliminary injunction motion. As ONY expects to show once it has that evidence, Chiesi and Cornerstone should not be allowed to hide behind the facade of integrity provided by the Journal's cache and its readers' quite understandable assumption that articles published therein meet academic standards and are the product of real science rather than paid results.

DATED: Buffalo, New York  
January 30, 2012

I Declare Under Penalty of Perjury  
that the Foregoing is True and Correct.

Executed on January 30, 2012

A handwritten signature in black ink, appearing to read "Edmund A. Egan", written over a horizontal line.

EDMUND A. EGAN, M.D.